

**COMBINED DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION
AND POWER OF ATTORNEY EXECUTED BY ASSIGNEE FOR REISSUE APPLICATION**

- ☐ Declaration Submitted with Initial Filing OR
☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16(e)) required)

As a representative for the assignee, I hereby declare that:

I believe the named inventors to be original, first, and joint inventors of the subject matter which is claimed and for which a reissue of U.S. Patent 5,399,346 (hereinafter "the original patent") is sought on the invention entitled:

GENE THERAPY

the specification of which:

- ☐ is attached hereto.
☒ was filed on November 4, 2003, as Application No. 10/701,022 and was amended on (if applicable).
☐ was filed by Express Mail No. as Application No. not known yet, and was amended on (if applicable).
☐ was filed on as PCT International Application No. PCT/ and was amended on (if any).

I have reviewed and understand the contents of the specification identified above, including the claim(s), as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Foreign priority benefits are claimed under 35 USC 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application(s) designating at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application(s) for patent, utility model, design registration, inventor's or plant breeder's rights certificate(s), or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter and having a filing date before that of the application(s) from which the benefit of priority is claimed.

| Prior Foreign Application Number(s) | Country | Foreign Filing Date (MM/DD/YYYY) | Priority Claimed | | Certified Copy Attached? | |
|--|---------|-------------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | | | YES | NO | YES | NO |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
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The original patent is believed to be partly invalid by erroneously claiming without deceptive intent more than the patentees had the right to claim. The patent is partly invalid because original claims 1, 2-6, 8-11, 13 and 14 are too broad. Specifically, claim 1, and dependent claims 2-6, 8-11, 13 and 14, are too broad because claim 1 recites "a therapeutic protein." In view of the above, claims 1-14 have been canceled and claims 15, 20, 25, 26, 30, and 31 have been added. The error in the patent, namely the inadvertent claiming of the invention more broadly than the patentees had a right to claim the invention is the result of error, without deceptive intent, on the part of the patentees. The error arose at the time that the patent application was prosecuted as a result of the failure to appreciate the impact on patentability of two prior art references, namely, Anderson et al., "*The ADA Human Gene Therapy Clinical Protocol*," (submitted to the Department of Health & Human Services on July 6, 1990), Human Gene Therapy, 1:331-332 (1990) (hereinafter "the ADA Protocol") and Rosenberg et al., "*Gene therapy of patients with advanced cancer using tumor infiltrating lymphocytes transduced with the gene coding for tumor necrosis factor*" (submitted to the Department of Health & Human Services on July 6, 1990) (hereinafter "the TNF Protocol"). The error was discovered after issuance of the patent, as a result of an interference proceeding involving the patent (specifically, Interference No. 104,712). In that interference proceeding, the Board of Patent Appeals and Interferences determined that (i) originally issued claims 1-5, 8, and 9 of U.S. Patent No. 5,399,346 are unpatentable as anticipated by the ADA Protocol and (ii) that originally issued claims 1-6, 8-11, 13, and 14 are unpatentable as anticipated by the TNF Protocol. Accordingly, the process claims of the instant reissue application have been amended in view of the disclosure of the ADA Protocol and in view of the disclosure of the TNF Protocol.

All errors being corrected in the reissue application up to the time of filing of this declaration arose without any deceptive intention on the part of the patentees.

The below-listed individuals are inventors in this reissue application with their respective residence and country of citizenship following.

| | |
|--|----------------------------|
| W. French Anderson, 6820 Melody Lane, Bethesda, MD 20817 | Country of Citizenship: US |
| Michael Blaese, 1986 Lancashire Drive, Rockville, MD 20854 | Country of Citizenship: US |
| Steven A. Rosenberg, 10104 Iron Gate Road, Potomac, MD 20854 | Country of Citizenship: US |

I hereby appoint Leydig, Voit & Mayer, Ltd. to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Customer No.:

45733

I further direct that correspondence concerning this application be directed the above-mentioned Customer Number.

I have reviewed the assignment records and certify that, to the best of my knowledge and belief, title of the original patent is vested in the United States of America as represented by the Secretary of the Department of Health and Human Services, as evidenced by the assignment recorded on February 15, 1996, at Reel 007666, Frame 0088, Reel 007662, Frame 0548, Reel 007662, Reel 0874, Reel 007662, Frame 0672, of the Assignment Division Records in the U.S. Patent and Trademark Office.

I am authorized to sign this document on behalf of the assignee, inasmuch as the National Institutes of Health, Office of Technology Transfer, has been duly delegated responsibility for patent matters under the authority of DHHS Secretary Louis W. Sullivan's May 21, 1991, memorandum published in the Friday, June 7, 1991, Federal Register Notices at Vol. 56, Pages 26418-26419 (copy attached).

In re Appln. of Anderson et al.
U.S. Patent Application No. 10/701,022
DHHS Ref. No. E-189-1989/3-US-04

I declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 6-27-07

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